OHRP: Who We Are, What We Do, and Why We Do it

Jaime O. Hernandez, J.D., M.Be.
Division of Education and Development (DED)
Office for Human Research Protections (OHRP)
October 31, 2019

Learning Objectives

- Explain the history and ethical principles that underlie the Federal regulations for human research protections
- Recognize the role of the HHS Office for Human Research Protections (OHRP)
- Understand the background of the revisions to the Common Rule
- Describe the basics of when research falls under the regulations with particular reference to the 2018 revisions

HHS Regulations On Protecting Human Subjects in Research

Ethical Challenge

Protecting the rights & welfare of individual research subjects so that they are not merely a means to an end

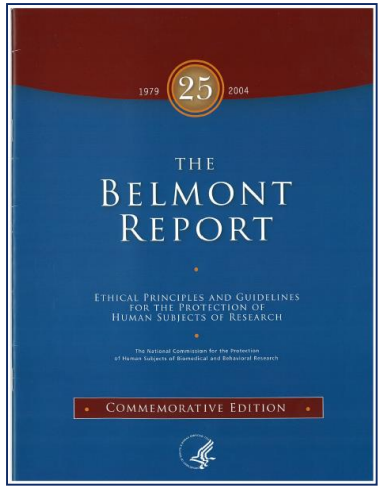
Furthering research to maximize societal benefits

Why Regulations?

The Need for Rules to Protect Research Participants

As a result of the public outcry from publicized cases of unethical research, Congress passed a **law requiring federal rules to protect people who participate in research**. The rules rely on ethical principles that were laid out in the ***Belmont Report***, which was written by an advisory committee created by Congress and published **in 1979**.

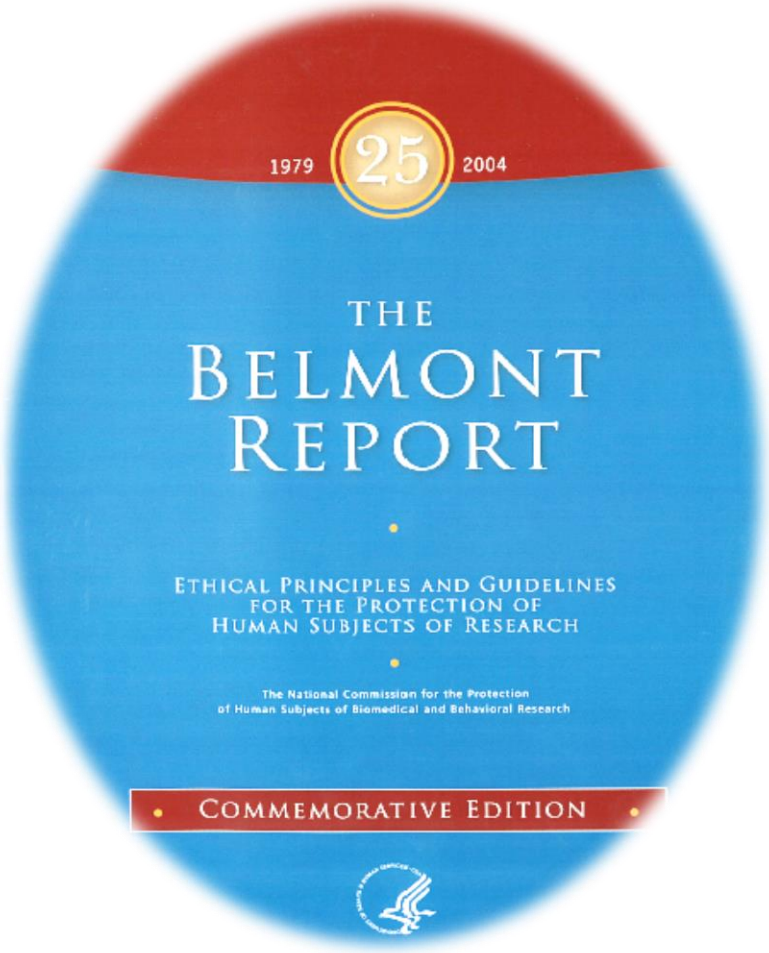
1979



Foundational Ethical Principles:

- **Respect for Persons**
- **Beneficence**
- **Justice**

Bioethical Principles Applied



Principles of the Belmont Report → **Requirements of 45 CFR 46**

Respect for Persons

- Informed Consent (information, understandability, & voluntariness)
- Subject's assent, permission from LAR

Beneficence

- Minimize risk of harm
- Favorable risk/benefit assessment

Justice

- Select individuals/groups of subjects equitably
- Link burdens to benefits

HHS Regulations on Human Research Protections: 45 CFR Part 46

HHS Regulations:

Subpart A – The Common Rule

Subpart B – Pregnant women & fetuses

Subpart C – Prisoners

Subpart D – Children

Subpart E – IRB Registration

Regulatory Authority:

Office for Human Research Protections (OHRP)

OHRP has a distinct role from these HHS agencies:

- **FDA** – regulates clinical investigations involving drugs, devices, and biologics
- **NIH** – conducts and supports research that must comply with OHRP regulations

2018 Revisions to the Common Rule

- Original Common Rule was promulgated in 1991
- Recently revised to:
  - Better protect research subjects and promote individual autonomy
  - Reduce administrative burden on IRBs
- General compliance date: **January 21, 2019**
  - Commonly referred to as: the **2018 Requirements**, the revised Common Rule, the new Rule, the revisions, etc.

What Version of the Common Rule Do I follow?

General Compliance date for 2018 Revisions to the Common Rule

Studies initiated* before this date must comply with the pre-2018 Requirements.

Studies initiated* after this date must comply with the 2018 Requirements.

Ongoing studies continue to comply with the pre-2018 Requirements (*unless institution determines to transition study(ies) to comply with 2018 Requirements*)

January 21, 2019

** Initiated = determined to be exempt, initially approved by an IRB, or granted a Secretarial Waiver*

Protecting Research Subjects: A Shared Responsibility

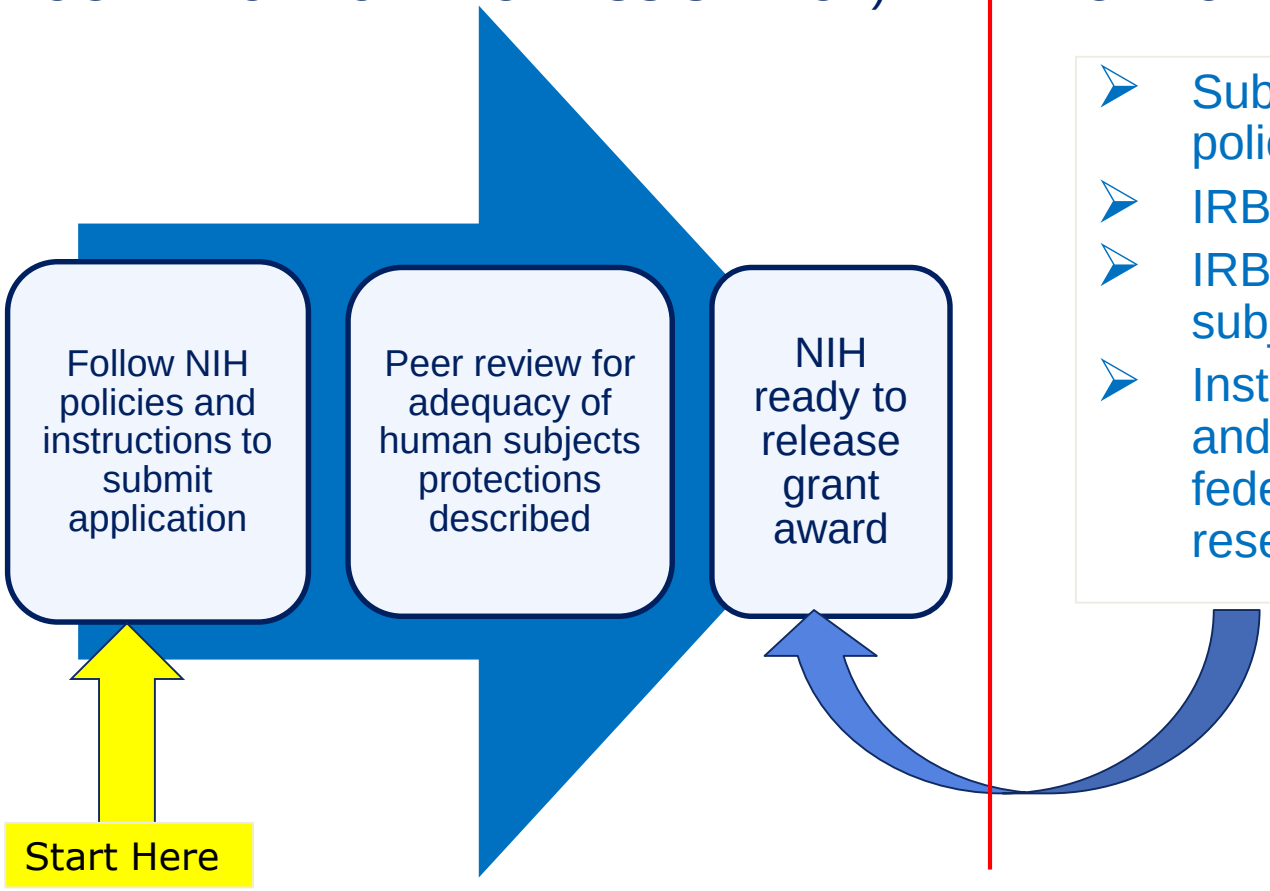
- Regulators
- Sponsors
- Research institutions
- IRBs
- Investigators

Shared Responsibility for HHS-funded Research: The Federalwide Assurance (FWA)

OHRP	Research Institutions	IRBs	NIH
Requires institutional assurance of compliance with the regulations through an active FWA	Commit to the ethical treatment of human subjects Maintain an active FWA Ensure that a registered IRB reviews and approves the research of its employees and agents May "check the box"	Review, approve, and oversee the research May apply institutional policies beyond the requirements of the Common Rule	Requires sponsored research to comply with 45 CFR 46 when applicable

Overview of the Human Subjects Review Process for NIH Grant Applications

NIH PEER REVIEW (CONTACT NIH PROGRAM OFFICER FOR ASSISTANCE)



IRB PROCESS (CONTACT IRB OFFICE FOR ASSISTANCE)

- Submit study to IRB office according to institutional policies
- IRB reviews, as appropriate
- IRB reviews and approves non-exempt human subjects research according to regulatory criteria
- Institution must provide certification of IRB review and approval for non-exempt HSR to NIH before federal money can be used to do human subjects research

Institution must provide certification of IRB review and approval for non-exempt HSR to NIH before federal money can be used to do human subjects research

Welcome

Glad you're here!